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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/587,864

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EXAMINER

BADR, HAMID R

ART UNIT

PAPER NUMBER

1781

NOTIFICATION DATE

DELIVERY MODE

04/14/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/587,864	Applicant(s) COLAVIZZA ET AL.	
	Examiner HAMID R. BADR	Art Unit 1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' amendment filed 01/15/2010 is acknowledged.

The rejection under 35 U.S.C. 112 first paragraph regarding the availability of the microorganisms is hereby withdrawn. The Applicants' statement of availability has been considered.

Claims 17-41 are being considered on the merits.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

1. Claims 17-19 are rejected under 35 U.S.C. 102(a) over applicant's admissions at page 2 of the specification.
2. The rejection is maintained for the reasons of record. The applicants admit that the strains were deposited in 2003, and there is no means for the Patent Office to know which inventor or inventors contributed to which strains, or if they all did.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. Claims 17-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Satoshi et al. (1994, Construction from a single parent of Baker's yeast strains with high freeze tolerance and fermentative activity in both lean and sweet doughs; hereinafter R1) in view of Hill (US 4, 318,991; hereinafter R2).

5. R1 investigates the hybridization process for generating hybrid *Saccharomyces cerevisiae* strains highly resistant to high sugar content in bread doughs. The hybrid baker's yeast strains as developed through hybridization can efficiently ferment doughs containing 30% sugar (Abstract, Materials and Methods, Table 1). R1 discloses the preparation of doughs using the developed strains. (Ingredients of doughs, Table 1 and dough raising test. Page 3500, col. 1).

6. R1 is silent regarding the tolerance of the developed strains to preservatives (mold inhibitors) such as propionates and sorbates and also the preparation of various forms of baker's yeast.

7. R2 discloses a method in which baker's yeast is propagated in the presence of carboxylic acids having 2-4 carbon atoms such as propionic acid. Such baker's yeast is claimed to tolerate the antifungal carboxylic acids (e.g. propionic) during dough fermentation. (Col. 4, lines 13-33).

8. R2 also discloses a process for the preparation of compressed yeast and dry baker's yeast. (Col. 3, Lines 55-68).

9. It is also noted that calcium propionate has been known and used as antifungal compound in the baking art.

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10. Since hybridization of yeasts for developing hybrid strains having high sugar tolerance and adaptation to the presence of organic acids such as propionic acid were known at the time the invention was made, it would have been obvious to develop hybrids of baker's yeast to tolerate high sugar concentration in bread dough as disclosed by R1 and propagate such strains in the presence of propionic acid as taught by R2. One would do so to acquire both high sugar tolerance and preservative tolerance in baker's yeast. Absent any evidence to contrary and based on the combined teachings of the cited references there would have been a reasonable expectation of success in developing the claimed *Saccharmyces cerevisiae* strains.

Response to Arguments

Applicants arguments have been thoroughly reviewed. These arguments are not deemed persuasive for the following reasons.

1. Applicants argue that upon the filing of the application, an executed Declaration signed by all inventors was submitted indicating that all inventors contributed the claimed invention. Thus, the signed Declaration is sufficient evidence that all inventors contributed to the claimed invention.

a. Since the strain was publicly deposited (and thus isolated, known & useable) in 2003, this is clear evidence that it was known and available, i.e. anticipated. Regarding Applicants' statement that their oath/declaration should suffice as evidence that all inventors contributed to the invention, it is noted that there are several claims directed to different aspects of the invention, including making bread dough incorporating the

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strain, etc. There is no evidence on the record that each inventor contributed to the actual strains claimed and rejected.

2. Regarding the 103 rejection, applicants argue that the method used by R1 is very different from the method used in the present application.

a. R1 discloses baker's yeast strains which are highly sugar and freeze tolerant.

It is noted that “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process”, *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) .

Further, “although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product”, *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983). See MPEP 2113.

Therefore, absent evidence of criticality regarding the presently claimed process and given that R1 meets the requirements of the claimed composition, R1 clearly meets the requirements of present claims 17-22, 24-27, 29-33, 35-41.

3. Applicants argue that the level of sugar tolerance in the strains disclosed by R1 is not known.

a. By referring to Table 1 of R1, it is clear that the sweet dough contains 16.2% (w/w) sugar which meets the requirement of 15% sugar in present claim 27.

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4. Applicants argue that R2 teaches how to propagate yeast in the presence of organic acids but does not disclose any method of producing new yeast strain.

a. The production of strains which are both sugar and freeze tolerant is disclosed by R1. R2 is a secondary reference which does not have to disclose all of the features of the presently claimed invention.

However, note that while R2 does not disclose all the features of the present claimed invention, R2 is used as teaching reference, and therefore, it is not necessary for this secondary reference to contain all the features of the presently claimed invention, *In re Nieveit*, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973), *In re Keller* 624 F.2d 413, 208 USPQ 871, 881 (CCPA 1981). Rather this reference teaches a certain concept, and in combination with the primary reference, discloses the presently claimed invention.

5. Applicants argue that despite the Examiner's statement that R1 teaches how to obtain strains with a high sugar tolerance, R1 does not in fact disclose such strains.

a. Applicants are referred to Table 4 for hybrids showing high sugar and freeze tolerance.

6. Applicants argue that in the instantly claimed invention the performance of the strains according to the invention is assessed in a dough containing even more sugar, namely 40% sugar in the PT2 test.

a. It is agreed that the composition of the dough in PT2 test contains about 19.6% (w/w) sugar while the sweet dough composition of R1 contains about 16.2% (w/w) sugar. However, the weight ratio of sugar to yeast in the composition of PT2 test is about 4.4 compared to the same ratio in sweet dough composition of R1 which is 10.

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Therefore, it is clear that the strains of R1 are 2.5 times more efficient than the presently claimed strains.

7. Applicants argue that from the data, it can be reasonably inferred that the strains presently claimed are more efficient regarding the assessment of the proof time, which the applicants believe is more relevant for the bread baking implementation.

a. The efficiency of strains as disclosed by R1 and as presently claimed was compared regarding the ratio of sugar to yeast in the compositions of R1 and composition in PT2. Strains of R1 are more efficient.

The comparison of strains of R1 and present invention regarding proof time can not be absolutely made because the experiments employ different controls (control strains are different), different criteria for assessment (proof time vs CO₂ evolved) and different sugar to yeast ratios. It is not logical to compare those experiments and conclude what the applicants are trying to conclude.

In conclusion, the idea of developing sugar and freeze tolerant baker's yeast through known techniques in the art and the isolated strains with high sugar and freeze tolerance, as disclosed by R1, together with methods of adaptation of yeasts to tolerate the inhibiting concentrations of organic acids (mold inhibitors) were known in the art at the time the presently claimed invention was made and that the developed strains, as disclosed by R1, are more efficient than the presently claimed strains. Therefore, the presently claimed invention is obvious in light of the references cited.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R Badr
Examiner
Art Unit 1794

/Keith D. Hendricks/

Supervisory Patent Examiner, Art Unit 1781